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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/589,384	06/07/2000	Hanspeter Heiniger	6748	8438

25763 7590 09/07/2005

DORSEY & WHITNEY LLP  
INTELLECTUAL PROPERTY DEPARTMENT  
50 SOUTH SIXTH STREET  
MINNEAPOLIS, MN 55402-1498

EXAMINER
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MAIORINO, ROZ

ART UNIT	PAPER NUMBER
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3763

DATE MAILED: 09/07/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>		<b>Applicant(s)</b>	
	09/589,384		HEINIGER ET AL.	
	<b>Examiner</b>		<b>Art Unit</b>	
	Roz Maiorino		3763	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 6/20/05.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 28-75 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 28-54 is/are allowed.
- 6) ☒ Claim(s) 55-75 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |                                                                                         |                                                                             |
|-----------------------------------------------------------------------------------------|-----------------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                        | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date: _____                                                |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date: _____                                                            | 6) <input type="checkbox"/> Other: _____                                    |

## DETAILED ACTION

### *Claim Rejections - 35 USC § 102*

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

1. Claims 55, 59-69, 72-75 is rejected under 35 U.S.C. 102(b) as being clearly anticipated by US Patent No. 5674203 to Lewandowski or US Patent No. 6547764 to Larsen et al.

Lewandowski and Lewandowski both teach the invention.

Larsen discloses a protected needle assembly. This apparatus contains a housing, a container for product, where the container is accommodated by housing, an injection needle 28 connected to container and protruding beyond the housing, a needle protection sleeve 32, and an indicator 55/51/38/84, which indicates to a user that a needle protection sleeve is in its distal position. An indicator, which is visibly, indicates to the user of the apparatus. (Figures 7-9)

Larsen discloses a protected needle assembly. This apparatus contains a housing, a container for product, where the container is accommodated by housing, an injection needle 8 connected to container and protruding beyond the housing, a needle protection sleeve 10, and an indicator (Col. 11, 45-60, and claim 1), which indicates to a

Art Unit: 3763

user that a needle protection sleeve is in its distal position. An indicator, which is visibly, indicates to the user of the apparatus.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 56-58, 70-71 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent NO.5674203 to Lewandowski , and further in view of U.S. Patent No. 6287283 to Ljunggreen et al or US Patent Pub NO. 2002/0002344 A1 to Douglas et al.

Both Lewandowski and Hjertman indicator's are manual apparatus for the movement of the needle and the indicator positioning of the needle. It would be obvious to modify the manual apparatus and utilize electronic means of defining the position of the needle, because most of the syringes have modified to become digital. One example is Ljunggreen, which discloses an apparatus for the registration of the setting of a medical device. Ljunggreen utilized a digital electronic display as is common and in practice.

Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to switch form manual to electronic, because as stated by Ljunggreen digital on the electronic display are more legible in relation to small indicators on the adjustment sleeve. Also, misalignment of this scale in relation to the

Art Unit: 3763

rim of the outer sleeve might occur. This is obviated according to the invention by the great digits on the display. (Col.4, lines 36-42). Furthermore it has been held that broadly providing a mechanical or automatic means to replace manual activity, which as accomplished the same result, involves only routine skill in the art. *In re Venner*, 120 USPQ 192.

***Allowable Subject Matter***

3. Claims 28-54 allowed.

***Response to Arguments***

4. Applicant's arguments filed 9/27/2004 have been fully considered but they are not persuasive.

- a. In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., indicator to indicate the position of the needle guard) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). Applicant only claims "indicator which indicates to the user ....that the needle protection sleeve is in the distal position" when the sleeve is not locked in Larsen or Lewandowski that is a indicator that the sleeve is or is not in the distal position.

Art Unit: 3763

- b. Applicant alleges the examiner has failed to point out the visual indicator, however as indicated above and in the past office action the indicator can be seen in figures 7-9.

### ***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Roz Maiorino whose telephone number is 571- 272-4960. The examiner can normally be reached on 9am-5:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nicholas Lucchesi can be reached on 703-308-2698. The fax phone

Art Unit: 3763

number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

RM



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